



**Australian Government**

**Department of Health**  
Therapeutic Goods Administration

**THERAPEUTIC GOODS ACT 1989, S.19(1)(a) EXEMPTIONS FOR SPECIAL AND EXPERIMENTAL USES  
APPROVAL TO SUPPLY UNDER THE SPECIAL ACCESS SCHEME**

**Drug:** Sodium Phenylbutyrate

**Dosage Regimen:** 4.5ml four times daily

**Duration:** 12 Months

**Dose Form:** oral liquid

Yours sincerely,

Signed and authorised by  
Andrew Leaver  
Delegate of the Secretary  
Prescription Medicines Authorisation Branch  
Email: [sas@tga.gov.au](mailto:sas@tga.gov.au)  
22-May-2017